MAR 1 6 2001

American Biocurve, Inc.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K010223**

Applicant information:

Date Prepared:	February 23, 2001
Name:	**American Biocurve, Inc.**
Address	15970 Bernardo Center Drive San Diego, CA 92127
Contact Person:	Mr. John Kenyon
Phone number:	(800) 959-2020
USA Consultant:	Med-Vice Consulting, Inc. Martin Dalsing, President 623 Glacier Drive Grand Junction, CO
Phone number	(970) 243-5490
Fax number	(970) 243-5501

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**Biocurve Soft (methafilcon A) Spherical and Toric Soft Contact Lens for Daily Wear (clear, lathe-cut)**

Purpose of 510(k) Submission:

American BioCurve, Inc. proposes to begin in approximately 90 days from the date of this 510(k) notification, the implementation of the release mechanism, "Controlled Process Release (Parametric Release)" for all Soft Contact Lens manufactured at the American BioCurve facility. All documentation required by the FDA to substantiate the conversion to "Controlled Process Release (Parametric Release)", follows in this 510(k) notification.

Equivalent Device:

This is a process change notification. The Biocurve Soft (methafilcon A) Spherical and Toric Soft Contact Lens was previously approved under American Biocurve, Inc. 510(k) # K001585.

Device Description:

The ionic lens material, (methafilcon A) is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and Methacrylic Acid, cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 45% methafilcon A and 55% water by weight when immersed in normal buffered saline solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 55% water by weight. The physical properties of the lens are:

Refractive Index	1.411 (hydrated)
Light Transmission	greater than 95%
Water Content	55 % ± 2%
Specific Gravity	1.09
Oxygen Permeability	18.8×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (Revised Fatt Method).

Intended Use:

The **Biocurve Soft (methafilcon A) Spherical** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **Biocurve Soft (methafilcon A) Toric** Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10 diopters.

Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Release Mechanism 'Parametric Release' Testing Data Summary:

American Biocurve, Inc. has conducted the required testing of the sterilization system to support the process change to 'Parametric Release'. Documentation and/or testing consisted of the following:

- Protocol for Parametric Release
- Shelf life data
- Steam Sterilization validation supporting a sterility assurance level (SAL) of 10^{-6}
- Average Bioburden level per lens
- Revised SOP's reflecting the process change

The bioburden level has been evaluated, an average lens bioburden of less than 20 spores and less than 1000 vegetative organisms per lens was demonstrated.

SUMMARY ~

Based on the intended use, product, and the steam sterilization validation data supporting a sterility assurance level of 10^{-6} provided in this notification, the conversion to controlled process release mechanism (Parametric Release) has been demonstrated to be a safe and effective method of providing a sterile device on a consistent basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2001

American Biocurve, Inc.
c/o Mr. Martin Dalsing
President, Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K010223
Trade Name: Biocurve Soft (methafilcon A) Spherical and Toric Soft Contact Lens for Daily Wear (clear, lathe-cut) - Parametric Release Process
Regulatory Class: II
Product Code: 86 LPL
Dated: January 16, 2001
Received: January 24, 2001

Dear Mr. Dalsing:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

American Biocurve, Inc.

INDICATIONS FOR USE STATEMENT

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(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature], Ph.D

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010223

Prescription Use ✓ or Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)